

**UNITED STATES DEPARTMENT OF AGRICULTURE**  
**FOOD SAFETY AND INSPECTION SERVICE**  
WASHINGTON, DC

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**DISTRICT MANAGER RESPONSIBILITIES IN ASSESSING AN ESTABLISHMENT'S  
RESPONSE TO A "NOTICE OF INTENDED ENFORCEMENT" (NOIE)**

***I. What is the purpose of this notice?***

This notice addresses District Managers' (DM) responsibilities in assessing and responding to an establishment's response to a "Notice of Intended Enforcement" (NOIE).

***II. What is an NOIE?***

**A.** An NOIE provides notification to an establishment that there is a basis for FSIS to withhold the marks of inspection and to suspend inspection as specified in 9 CFR 500.4. The information in the NOIE meets the notification requirements of 9 CFR 500.5.

**B.** A DM issues an NOIE to establishments for noncompliances that do not pose an imminent threat to public health but that may warrant the withholding or suspension of inspection if not corrected. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on an agreement with the establishment, the DM may extend the three business days if he or she believes this is necessary.

***III. What should a DM do when he or she receives an establishment's response to an NOIE?***

**A.** The DM should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM is to determine whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DMs should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM should consider the plant's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DMs are

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encouraged to contact staff members from Technical Service Center, the Office of Public Health and Science, and the Office of Policy, Program Development and Evaluation for assistance in making decisions.

B. Upon assessing and evaluating the establishment's response, the DM may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM guidance on what procedures to follow:

*1. Under what circumstances should a DM accept the establishment's response?*

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a description of acceptable corrective and preventive actions from which the DM can find that compliance will be achieved upon implementation, the DM can accept the response, notify the establishment of the decision, and close the matter with a letter of information to the establishment.

*2. Under what circumstances could a DM implement an enforcement action?*

If the establishment does not respond or based on the DM's assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving:

- a. withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.
- b. suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.

*3. Under what circumstances can a DM defer an enforcement decision?*

a. A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive action may be adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to find that the proposed plan, once executed, will prevent reoccurrence. In this situation, a DM may choose to defer his or her enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM is expected to make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM should not defer a decision for more than 90 days without cause. The DM is to notify the establishment in writing as to why he or she deferred a decision.

b. If the DM determines that the establishment's plan is adequate, the DM should follow III.B.1. above.

c. If, at any time, during a period of deferment, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM will immediately notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

**IV. *Under what circumstances could the DM hold a suspension in abeyance?***

**A.** When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. the establishment presents a plan that demonstrates to the satisfaction of the DM that the establishment has designed corrective and preventive actions that appear adequate to eliminate the noncompliance and ensure that it will not reoccur; and

2. it is necessary to allow the establishment to operate after implementing these preventive and corrective actions so the DM can determine whether the establishment is able to adequately execute the plan. The DM should not hold a suspension in abeyance for more than 90 days without cause.

**B.** If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

**C.** If the DM decides to put the suspension in abeyance and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. If this occurs, the DM will instruct the IIC to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM will also contact the Assistant Deputy Administrator for District Enforcement Operations.

/s/ Philip S. Derfler

Deputy Administrator  
Office of Policy, Program Development  
and Evaluation